

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

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| <i>In re</i> Application of: |) | Confirmation No. 8424 |
| |) | |
| Cooper, Mark J., et al. |) | Group Art Unit 1633 |
| |) | |
| Serial No. 10/656,192 |) | Examiner: Long, Scott |
| |) | |
| Filing Date: September 08, 2003 |) | Att'y. Dkt. No. 003659.00029 |

FOR: LYOPHILIZABLE AND ENHANCED COMPACTED NUCLEIC ACIDS

REPLY BRIEF

U.S. Patent and Trademark Office
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

Appellants respond to the Examiner's Answer mailed October 16, 2009. Therefore this reply is timely filed.

A separate paper requests an Oral Hearing. Charge any required fees to our Deposit Account No. 19-0733.

STATUS OF CLAIMS

Claims 1-5, 8-14, 17-19, 26, 28, 30-31, 34-35, 38-40, 51-55, 58-70, 73-82, 103-104, 106-107, 114-115, and 122 are pending. Claims 6-7, 15-16, 20-25, 27, 29, 32-33, 36-37, 41-50, 56-57, 71-72, 83-102, 105, 108-113, 116-121, and 123 are cancelled. All pending claims are rejected.

A restriction requirement and election of species has focused the examination on the species: acetate counterion, cDNA nucleic acid molecule, and CK15-60P10 polycation. As far as the record reveals, examination has been limited to the elected species, and the requirement has not been withdrawn. Therefore, the assertion of other counterions in cited references for the first time in the Appeal Brief is inappropriate.

GROUND OF REJECTION TO BE REVIEWED

- I. Whether Hanson¹ anticipates claims 1, 2, 8, 9, 11, 12, 17, 18, 26, 28, 30, 34, 38, 53, 65, 78, and 103 under 35 U.S.C. §102(b)
- II. Whether Hanson, Park², and Schacht³ render claims 3, 10, 19, 31, 35, 51-53, 63-65, 67, 68, 76-78, and 104 obvious under 35 U.S.C. §103(a)
- III. Whether Hanson, Park, and Mao⁴ render claims 58-62, 66, 73-75, 79-82, and 122 obvious under 35 U.S.C. §103(a)
- IV. Whether Hanson, Park, Schacht, and Kwoh⁵ render claims 4-5, 13-14, 39-40, 54-55, 69-70, 106-107, 114-115 obvious under 35 U.S.C. §103(a)

¹ U.S. 5,844,107

² U.S. 6,177,274

³ WO1998/19710

⁴ *J. Controlled Release* 70: 399-421 (2001)

⁵ *Biochimica et Biophysica Acta* 1444: 171-190 (1999)

ARGUMENT

The Examiner's Answer maintains that Hanson (U.S. 5,844,107) teaches the claimed complexes having the recited properties of the independent claims. The Examiner's Answer asserts that the appealed claims are product-by-process claims; therefore, it is not necessary for the Office to find the same method of making in the prior art; rather a teaching of the same structure of the product is sufficient to anticipate.⁶

Structure of complexes

The Examiner's Answer⁷ relies on a phrase from Hanson's legend of Table 104, at column 62: "the structure resulting from the condensation are rod-like **relaxed** toroids of increased size (**Relaxed**).⁸" These are the same structures referred to in Table 103, at column 57, which are described as "**Relaxed** complex (caused by excess salt)" in the first column, and as "Rod-like fibers (usually 10-20 times the diameter of a naked DNA fiber, i.e., usually 10-20 nm thick, and longer than 60 nm) of DNA and branched toroidal structures of increased size (FIG 1F)" in the fourth column. These are the same complexes that are described at column 6, lines 11-16: "In Fig. 1F, we see a DNA complex, at a concentration of 1.068 M NaCl, which is above optimal for condensation of this complex. The DNA is in the **relaxed** state. Note the branched unimolecular toroids in which a nucleus of condensation is visible and the rod-like DNA fibers." These are further explained in Example 1, column 27, lines 34-37: "If the ionic strength is increased above the critical range required for the condensation of the DNA complex, the complex assumes a **non-condensed, relaxed** conformation (FIG. 1F)."⁸

⁶ Paragraph spanning pages 25 and 26

⁷ Paragraph spanning pages 23 and 24

⁸ Emphasis added in the quotes of the preceding paragraph

The Examiner's Answer states, "The Office interprets these teachings as satisfying the structural limitations of the instant claims."⁹ These structures of Hanson, however, cannot be the same as those claimed because they are relaxed. All of the appealed claims recite, "[N]ucleic acid molecules of the rod-shaped complexes are **condensed**."

Hanson defines the terms relaxed and condensed:

Condensed DNA is in a state in which interaction with the solvent is minimal and therefore the DNA is in the form of isolated spheres or toroids. It is not fibrous to an appreciable degree. Relaxed DNA, typically formed by dissociation of polycation from the DNA, forms fibers. Aggregated DNA forms clumped or multimolecular toroids.

Column 19, lines 60-65.

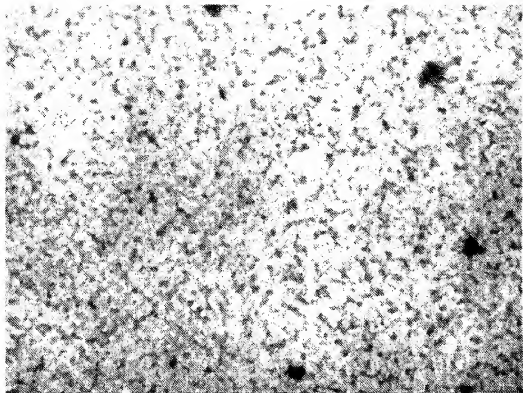
The relaxed DNA of Hanson cannot anticipate the condensed nucleic acids of the appealed claims.

Visually, the Hanson complexes do not resemble the claimed complexes. Hanson Fig. 1F shows dense spherical particles with unraveling fibers of DNA escaping from the main body.¹⁰

⁹ Page 24, lines 4-5 and page 27, lines 11-12

¹⁰ See particles at approximately 2, 4 and 6 o'clock

FIG.1F



The complexes of the present invention are rod shaped complexes having a diameter of 10-20 nm, as shown below from Figure 10.

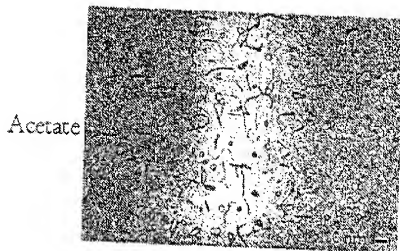


Fig. 10

Thus, structurally, the Hanson complexes are not rod-shaped complexes, but rather have rod-shaped fibers protruding from spherical or toroidal complex bodies. Further, the Hanson

complexes contain relaxed nucleic acids rather than condensed. Structurally, Hanson fails to teach complexes that meet all the limitations of the subject claims.

Respectfully submitted,

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Date: December 15, 2009

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